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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/878,603

Applicant(s)

WARD ET AL.

Examiner

Amy M. DeCloux

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## **DETAILED ACTION**

Claims 1-2 are pending.

### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-2, in Paper No. 12, filed 11-15-02, is acknowledged.

Applicant cancelled non-elected claims 3-11 in the Amendment filed 11-15-02 (Paper No. 12).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Priority***

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Specifically, reference must be made to parent application 09/387,671.

### ***Information Disclosure Statement***

A) It is noted that references numbered 25, 36, 51-53 and 67 of the information disclosure statement filed 11-15-02 (Paper No. 13), fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specifically, there is no paper copy of references numbered 51-53. Further references numbered 25, 36 and 67 contain the Title page only, and thus have not been considered further than said Title pages.

B) It is noted that the reference numbered 14 of the information disclosure statement filed 11-15-02 (Paper No. 13), fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered. Specifically Patent EP 025949 is not in English and there is no English Abstract.

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C) The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specifically, it is noted that most of the several references that have been cited throughout the specification, have been cited in the 1449 form filed 11-15-03 (Paper No. 13), and thus have been considered. However, those references not on said 1449 have not necessarily been considered.

D) Also, pages 2-9 of the response filed 11-15-03 (Paper No. 12), lists several references which are not cited on said 1449 form and which fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Specifically, antecedent basis is lacking for a composition comprising a portion of a peptide defined by SEQ ID NO:14 and SEQ ID NO:15, recited in claim 1 and dependent claim 2. It is suggested that the Applicants amend the specification to include this limitation, in order to overcome this rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 1 and dependent claim 2, recite the limitation "SEQ ID NO:14 and SEQ ID NO:15, and portions thereof" in lines 2-3 of claim 1. There is insufficient antecedent basis for this limitation in the claim. Specifically the instant specification does not appear to disclose a composition comprising portions of SEQ ID NO:14 and SEQ ID NO:15.

B) Claim 1 and dependent claim 2, are indefinite for being in improper Markush format. By reciting the phrase "from the group of SEQ ID NO:14 and SEQ ID NO:15, and portions

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thereof" in line 2 of claim 1, the Markush group encompasses only SEQ ID NO:14 and SEQ ID NO:15. Therefore, the instant claims may encompass a composition comprising multiple peptides, such as a peptide defined by SEQ ID NO:14 and portions thereof, or a peptide defined by SEQ ID NO:15 and portions thereof; though based on the specification, this interpretation does not appear to be what Applicant intended. The Office recommends substituting the phrase "from the group consisting of SEQ ID NO:14, SEQ ID NO:15 and a portion thereof". See MPEP 2173.05(h).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 is drawn to a composition comprising an isolated and purified peptide defined by an amino acid sequence selected from the group of SEQ ID NO:14 and SEQ ID NO:15, and portions thereof, wherein said peptide is specific for the C5a receptor.

However, the instant disclosure describes no portion or fragment of a peptide defined by the amino acid sequence of SEQ ID NO:14 or SEQ ID NO:15, and thus does not adequately describe the scope of the claimed genus of portions of said peptide. It is noted that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Though the instant claim is drawn to a peptide and not a cDNA, the same principle applies.

The instant specification discloses that full length human C5a is 74 amino acids long, and that the recited SEQ ID NO:14 and SEQ ID NO:15 represents positions 12-20 and 28-33, respectively of Human C5a (see page 24). The instant specification also discloses three peptides fragments of human C5a: (SEQ ID NO: 4, 5, and 6 which represent residues 1-20, 21-40 and 55-74, respectively), and also discloses that peptides consisting of SEQ ID NO:4 and SEQ ID NO:5, but not SEQ ID NO:6, are able to compete with human C5a in binding neutrophils (see page 45) presumably through the C5a receptor on neutrophils since the specification discloses the

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interaction of C5a peptide with the C5a receptor on neutrophils (see first full paragraph of page 13). The specification does not teach which residues of SEQ ID NO: 4 or SEQ ID NO:5 are essential for peptide binding to the C5a receptor. It is noted that SEQ ID NO: 4 or SEQ ID NO:5 comprise the recited sequences of SEQ ID NO:14 and SEQ ID NO:15, respectively.

Chen et al (Journal of Biochemistry, 273(17):10411-19 (1998)) teaches that the recognition site of C5a for the C5a receptor has not been defined conclusively because the important residues were distributed almost throughout C5a (see entire article, including column 1, paragraph 2). Therefore, portions of SEQ ID NO:14 and SEQ ID NO:15 which are specific for the C5a receptor are not conventional in the art. Because said portions are not conventional in the art, and because the specification does not describe any fragment or portion of SEQ ID NO:14 or 15, nor does it teach the requisite residues within SEQ ID NO:14 or SEQ ID NO:15 critical for binding to the C5a receptor, one of skill in the art would not recognize from the disclosure that applicant was in possession of a composition comprising an isolated and purified portion of a peptide defined by an amino acid sequence selected from the group of SEQ ID NO:14 and SEQ ID NO:15 wherein said peptide is specific for the C5a receptor encompassed by the claimed invention.

Therefore, there is insufficient written description for a composition comprising an isolated and purified portion of a peptide defined by an amino acid sequence selected from the group of SEQ ID NO:14 and SEQ ID NO:15, wherein said peptide is specific for the C5a receptor, as recited in claim 2.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Merriam Webster's Collegiate Dictionary, Tenth Edition, 1996 page 1305, column 1, lines 4-6.

Said Dictionary teaches the amino acid valine, which is a one amino acid fragment of both SEQ ID NO:14 and 15. Therefore, the referenced teachings anticipate the claimed invention. The examiner notes the lack of functional language in claim 1.

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***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

*Amy DeCloux 2-8-03*  
Amy DeCloux, Ph.D.  
Patent Examiner, Group 1640  
February 8, 2003